

Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (Text with EEA relevance)

PART IV

**REGISTRATION, APPROVAL, TRACEABILITY AND MOVEMENTS**

TITLE II

**AQUATIC ANIMALS AND PRODUCTS OF ANIMAL ORIGIN FROM AQUATIC ANIMALS**

*CHAPTER 1*

***Registration, approval, record-keeping and registers***

*Section 1*

***Registration of aquaculture establishments***

*Article 172*

**Obligation of operators to register aquaculture establishments**

1 Operators of aquaculture establishments shall, in order for their establishments to be registered in accordance with Article 173, before they commence such activities:

- a inform the competent authority of any aquaculture establishment under their responsibility;
- b provide the competent authority with the following information:
  - (i) the name and address of the operator concerned;
  - (ii) the location of the establishment and a description of its facilities;
  - (iii) the species, categories and quantities (numbers, volume or weight) of aquaculture animals which they intend to keep on the aquaculture establishment and the capacity of the aquaculture establishment;
  - (iv) the type of aquaculture establishment; and
  - (v) any other aspects of the establishment which are relevant for the purpose of determining the risk posed by it.

2 Operators of aquaculture establishments referred to in paragraph 1 shall inform the competent authority in advance of:

- a any significant changes in the aquaculture establishment in question concerning the matters referred to in point (b) of paragraph 1;

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b any cessation of activity by the operator or aquaculture establishment concerned.

3 Aquaculture establishments which are subject to approval in accordance with Article 176(1) and Article 177 shall not be required to provide the information referred to in paragraph 1 of this Article.

4 An operator may apply for registration as provided for in paragraph 1 to cover a group of aquaculture establishments, provided that they fulfil either of the following conditions:

- a they are located in an epidemiologically linked area and all operators in that area operate under a common biosecurity system;
- b they are under the responsibility of the same operator and operate under a common biosecurity system, and the aquaculture animals of the establishments concerned form part of a single epidemiological unit.

Where an application for registration covers a group of establishments, the rules laid down in paragraphs 1 to 3 of this Article and in point (b) of the first paragraph of Article 173, and the rules adopted pursuant to Article 175 which are applicable to a single aquaculture establishment, shall be applicable to the group of aquaculture establishments as a whole.

#### *Article 173*

### **Obligations of the competent authority concerning the registration of aquaculture establishments**

A competent authority shall register:

- (a) aquaculture establishments in the register of aquaculture establishments provided for in Article 185(1), where the operator concerned has provided the information required in accordance with Article 172(1);
- (b) groups of aquaculture establishment in that register, provided that the criteria laid down in Article 172(4) are complied with.

The competent authority shall assign each establishment or group of establishments as referred to in this Article with a unique registration number.

#### *Article 174*

### **Derogations from the obligation of operators to register aquaculture establishments**

By way of derogation from Article 172(1), Member States may exempt from the registration requirement certain aquaculture establishments posing an insignificant risk, as provided for in an implementing act adopted in accordance with Article 175.

#### *Article 175*

### **Implementing powers concerning derogations from the obligation to register aquaculture establishments**

1 The Commission may, by means of implementing acts, lay down rules concerning the information to be provided by operators for the purpose of the registration of aquaculture

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establishments as provided for in Article 172(1), including the time-limits by which such information is to be provided.

2 The Commission shall, by means of implementing acts, lay down rules concerning the types of aquaculture establishments that may be exempted by Member States from the registration requirement in accordance with Article 174, based on:

- a the species, categories and quantity (number, volume or weight) of aquaculture animals on the aquaculture establishment in question and the capacity of that establishment;
- b the movements of aquaculture animals into and out of the aquaculture establishment.

3 The implementing acts referred to in this Article shall be adopted in accordance with the examination procedure referred to in Article 266(2).

## *Section 2*

### ***Approval of certain types of aquaculture establishments***

#### *Article 176*

#### **Approval of certain aquaculture establishments and delegated acts**

1 Operators of the following types of aquaculture establishments shall apply to the competent authority for approval in accordance with Article 180(1):

- a aquaculture establishments where aquaculture animals are kept with a view to their being moved therefrom, either alive or as products of aquaculture animal origin;
- b other aquaculture establishments which pose a significant risk due to:
  - (i) the species, categories and number of aquaculture animals kept there;
  - (ii) the type of aquaculture establishment concerned;
  - (iii) movements of aquaculture animals into and out of the aquaculture establishment concerned.

2 By way of derogation from paragraph 1, Member States may exempt from the obligation to apply for approval operators of the following types of establishment:

- a aquaculture establishments producing a small quantity of aquaculture animals for supply for human consumption either:
  - (i) to the final consumer directly; or
  - (ii) to local retail establishments directly supplying the final consumer;
- b ponds and other installations where the population of aquatic animals is maintained only for recreational fishing purposes, by restocking with aquaculture animals which are confined and unable to escape;
- c aquaculture establishments keeping aquaculture animals for ornamental purposes in closed facilities,

provided that the establishment in question does not pose a significant risk.

3 Unless a derogation has been granted under paragraph 4 of this Article, operators shall not commence activity at an aquaculture establishment as referred to in paragraph 1 of this Article until that establishment has been approved in accordance with Article 181(1), and shall

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cease such activity at an aquaculture establishment referred to in paragraph 1 of this Article where:

- a the competent authority withdraws or suspends its approval in accordance with Article 184(2); or
- b in the event of conditional approval, granted in accordance with Article 183(3), the aquaculture establishment concerned fails to comply with the outstanding requirements referred to in Article 183(4) and does not obtain a final approval in accordance with Article 183(3).

4 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

- a derogations from the requirement for operators to apply to the competent authority for approval of the types of aquaculture establishments referred to in point (a) of paragraph 1, concerning types of establishments other than those specified in points (a)(i) and (ii) of paragraph 2, where those establishments do not pose a significant risk;
- b the types of aquaculture establishments which must be approved in accordance with point (b) of paragraph 1.

5 When adopting delegated acts as provided for in paragraph 4, the Commission shall base those acts on the following criteria:

- a the species and categories of aquaculture animals kept in an aquaculture establishment;
- b the type of aquaculture establishment and the type of production; and
- c typical movement patterns of the type of aquaculture establishment concerned and of the species or category of aquaculture animals concerned.

6 An operator may apply for approval of a group of aquaculture establishments, provided that the requirements provided for in points (a) and (b) of the first paragraph of Article 177 are complied with.

#### *Article 177*

##### **Approval by the competent authority of groups of aquaculture establishments**

The competent authority may grant approval as provided for in Article 181(1) covering a group of aquaculture establishments, provided that the aquaculture establishments in question comply with either of the following conditions:

- (a) they are located in an epidemiologically linked area and all operators in that area operate under a common biosecurity system; however, any on-shore or off-shore establishment for the reception, conditioning, washing, cleaning, grading, wrapping and packaging of live bivalve molluscs intended for human consumption (so-called 'dispatch centres'), establishment with tanks fed by clean seawater in which live bivalve molluscs are placed for the time necessary to reduce contamination to make them fit for human consumption (so-called 'purification centres') and similar establishments located inside such an epidemiologically linked area must be approved individually;
- (b) they are under the responsibility of the same operator; and
  - (i) operate under a common biosecurity system; and
  - (ii) the aquaculture animals of the establishments concerned form part of the same epidemiological unit.

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When a single approval is granted for a group of aquaculture establishments, the rules laid down in Article 178 and Articles 180 to 184 and the rules adopted pursuant to Articles 180(2) and 181(2), which are applicable to a single aquaculture establishment, shall be applicable to the whole group of aquaculture establishments.

#### *Article 178*

##### **Approval of status of confined aquaculture establishments**

Operators of aquaculture establishments wishing to obtain the status of a confined establishment shall:

- (a) apply to the competent authority for approval in accordance with Article 180(1);
- (b) move aquaculture animals to or from their establishment in accordance with the requirements provided for in Article 203(1) and any delegated acts adopted in accordance with Article 203(2) only after their establishment has obtained an approval of that status from the competent authority in accordance with Article 181 or 183.

#### *Article 179*

##### **Approval of disease control aquatic food establishments**

Operators of disease control aquatic food establishments shall:

- (a) ensure that the necessary approval in accordance with Article 4 of Regulation (EC) No 853/2004 of the European Parliament and of the Council<sup>(1)</sup> has been obtained; and
- (b) apply to the competent authority, in accordance with Article 180(1), for approval to slaughter or process aquatic animals for disease control purposes in accordance with point (b) of Article 61(1), Article 62 and Articles 68(1), 79 and 80 and the rules adopted pursuant to Article 63 and Articles 70(3) and 71(3).

#### *Article 180*

##### **Obligation of operators to provide information with a view to obtaining approval**

1 Operators shall, for the purposes of their application for approval of their establishment as provided for in Article 176(1), Article 177, point (a) of Article 178 and Article 179, provide the competent authority with the following information:

- a the name and address of the operator concerned;
- b the location of the establishment concerned and a description of its facilities;
- c the species, categories and quantities (numbers, volume or weight) of aquaculture animals relevant for the approval which are kept on the establishment;
- d the type of aquaculture establishment;
- e in cases of approval of a group of aquaculture establishments, details showing that the group in question complies with the conditions laid down in Article 177;
- f other aspects of the mode of operation of the aquaculture establishment in question which are relevant for determining the risk, posed by it;
- g the water supply to, and discharge of water from, the establishment;
- h the establishment's biosecurity measures.

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2 Operators of establishments as referred to in paragraph 1 shall inform the competent authority in advance of:

- a any changes in the establishments concerning the matters referred to in paragraph 1;
- b any cessation of activity by the operator or establishment concerned.

3 The Commission may, by means of implementing acts, lay down rules concerning the information to be provided by operators in their application for approval of their establishment, in accordance with paragraph 1, including the time-limits by which such information is to be provided.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

### *Article 181*

#### **Granting of, and conditions for, approval and delegated acts**

1 The competent authority shall only grant approvals of aquaculture establishments as referred to in Article 176(1) and point (a) of Article 178, groups of aquaculture establishments as referred to in Article 177 and disease control aquatic food establishments as referred to in Article 179, where such establishments:

- a comply with the following requirements, where appropriate, in relation to:
  - (i) quarantine, isolation and other biosecurity measures taking into account the requirements provided for in point (b) of Article 10(1) and any rules adopted pursuant to Article 10(6);
  - (ii) surveillance requirements as provided for in Article 24, where relevant for the type of establishment concerned and the risk involved, in Article 25;
  - (iii) record-keeping as provided for in Articles 186 to 188 and any rules adopted pursuant to Articles 189 and 190;
- b have facilities and equipment that are:
  - (i) adequate to reduce the risk of the introduction and spread of diseases to an acceptable level, taking into account the type of establishment concerned;
  - (ii) of a capacity adequate for the species, categories and quantity (numbers, volume or weight) of aquatic animals concerned;
- c do not pose an unacceptable risk as regards the spread of diseases, taking into account the risk-mitigation measures in place;
- d have in place a system which enables the operator concerned to demonstrate to the competent authority that the requirements laid down in points (a), (b) and (c) are fulfilled.

2 The Commission shall adopt delegated acts in accordance with Article 264 concerning:

- a quarantine, isolation and other biosecurity measures as referred to in point (a)(i) of paragraph 1;
- b surveillance as referred to in point (a)(ii) of paragraph 1;
- c facilities and equipment as referred to in point (b) of paragraph 1.

3 When establishing the rules to be laid down in the delegated acts to be adopted pursuant to paragraph 2, the Commission shall base those rules on the following matters:

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- a the risks posed by each type of establishment;
- b the species and categories of aquaculture or aquatic animals relevant for the approval;
- c the type of production concerned;
- d typical movement patterns of the type of aquaculture establishment and species and categories of animals kept in those establishments.

### *Article 182*

#### **Scope of the approval of establishments**

The competent authority shall expressly specify in the approval of an aquaculture establishment or a disease control aquatic food establishment granted pursuant to Article 181(1) following an application made in accordance with Article 176, Article 177, point (a) of Article 178 or Article 179:

- (a) for which of the types of aquaculture establishments referred to in Article 176(1) and point (a) of Article 178, groups of aquaculture establishments referred to in Article 177 and disease control aquatic food establishments referred to in Article 179, and in any rules adopted pursuant to point (b) of Article 176(4), the approval applies;
- (b) for which species and categories of aquaculture animals the approval applies.

### *Article 183*

#### **Procedures for the granting of approval by the competent authority**

1 The competent authority shall establish procedures for operators to follow when applying for approval of their establishments in accordance with Article 176(1) and Articles 178 and 179.

2 Upon receipt of an application for approval from an operator in accordance with Article 176(1), Article 178 or Article 179, the competent authority shall make an on-site visit.

3 Provided that the requirements referred to in Article 181 are fulfilled, the competent authority shall grant the approval.

4 Where an establishment does not fulfil all requirements for approval as referred to in Article 181, the competent authority may grant conditional approval of an establishment if it appears, on the basis of the application by the operator concerned and the subsequent on-site visit provided for in paragraph 2 of this Article, that the establishment meets all the main requirements that provide sufficient guarantees that the establishment does not pose a significant risk.

5 Where conditional approval has been granted by the competent authority in accordance with paragraph 4 of this Article, it shall grant full approval only where it appears from another on-site visit to the establishment, carried out within three months from the date of the grant of conditional approval, or from documentation provided by the operator within three months from that date, that the establishment meets all the requirements for approval provided for in Article 181(1) and the rules adopted pursuant to Article 181(2).

Where the on-site visit or the documentation referred to in the first subparagraph shows that clear progress has been made but that the establishment still does not meet all of those requirements, the competent authority may prolong the conditional approval.

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However, conditional approval shall not be granted for a period exceeding, in total, six months.

#### *Article 184*

##### **Review, suspension and withdrawal of approvals by the competent authority**

1 The competent authority shall keep approvals of establishments granted in accordance with Article 181(1) under review, at appropriate intervals based on the risk involved.

2 Where a competent authority identifies serious deficiencies in an establishment as regards compliance with the requirements laid down in Article 181(1) and the rules adopted pursuant to Article 181(2), and the operator of that establishment is not able to provide adequate guarantees that those deficiencies will be eliminated, the competent authority shall initiate procedures to withdraw the approval of the establishment.

However, the competent authority may merely suspend, rather than withdraw, approval of an establishment where the operator can guarantee that it will eliminate those deficiencies within a reasonable period of time.

3 Approval shall only be granted after withdrawal or restored after suspension in accordance with paragraph 2 when the competent authority is satisfied that the establishment fully complies with all the requirements of this Regulation appropriate for that type of establishment.

#### *Section 3*

##### ***Register of aquaculture establishments and disease control aquatic food establishments***

#### *Article 185*

##### **Register of aquaculture establishments and disease control aquatic food establishments**

- 1 Each competent authority shall establish and keep up to date a register of:
  - a all aquaculture establishments registered in accordance with Article 173;
  - b all aquaculture establishments approved in accordance with Article 181(1);
  - c all disease control aquatic food establishments approved in accordance with Article 181(1).
- 2 The register of aquaculture establishments provided for in paragraph 1 shall contain the following information:
  - a the name and address of the operator and the registration number of the establishment in question;
  - b the location of the aquaculture establishment or, as the case may be, of the group of aquaculture establishments concerned;
  - c the type of production at the establishment;
  - d the water supply to, and discharge from, the establishment, when relevant;
  - e the species of aquaculture animals kept at the establishment;
  - f up-to-date information on the health status of the registered aquaculture establishment, or, as the case may be, of the group of establishments, as regards the listed diseases referred to in point (d) of Article 9(1).



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3 For establishments approved in accordance with Article 181(1), the competent authority shall make publicly available by electronic means at least the information referred to in points (a), (c), (e) and (f) of paragraph 2 of this Article, subject to data protection requirements.

4 Where appropriate and relevant, a competent authority may combine the registration provided for in paragraph 1 with registration for other purposes.

5 The Commission shall adopt delegated acts in accordance with Article 264 concerning:

- a the relevant detailed information to be included in the register of aquaculture establishments provided for in paragraph 1 of this Article;
- b the public availability of that register.

#### *Section 4*

### ***Record-keeping and traceability***

#### *Article 186*

### **Record-keeping obligations of operators of aquaculture establishments**

1 Operators of aquaculture establishments subject to the requirement of registration in accordance with Article 173, or approval in accordance with Article 181(1), shall keep and maintain records containing at least the following information:

- a the species, categories and quantities (numbers, volume or weight) of aquaculture animals on their establishment;
- b movements of aquaculture animals and products of animal origin obtained from those animals into and out of their establishment, stating as appropriate:
  - (i) their place of origin or destination;
  - (ii) the date of such movements;
- c the animal health certificates, in paper or electronic form, required to accompany movements of aquaculture animals arriving at the aquaculture establishment in accordance with Article 208 and the rules adopted pursuant to points (a) and (c) of Article 211(1) and Article 213(2);
- d mortality in each epidemiological unit and other disease problems at the aquaculture establishment as relevant for the type of production;
- e biosecurity measures, surveillance, treatments, test results and other relevant information as appropriate for:
  - (i) the species and categories of the aquaculture animals on the establishment;
  - (ii) the type of production at the aquaculture establishment;
  - (iii) the type and size of the aquaculture establishment;
- f the results of any animal health visits required in accordance with Article 25(1).

The records shall be kept and maintained in paper or electronic form.

2 Aquaculture establishments presenting a low risk of spreading listed or emerging diseases may be exempted by the Member State concerned from the requirement to keep records

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of all or some of the information listed in points (c), (d) and (e) of paragraph 1, provided that traceability is ensured.

3 Operators of aquaculture establishments shall keep the records provided for in paragraph 1 on their aquaculture establishment concerned and shall:

- a keep them in such a way that the tracing of the place of origin and destination of aquatic animals can be guaranteed;
- b make them available to the competent authority on request;
- c retain them for a minimum period to be prescribed by the competent authority, which may not be less than three years.

By way of derogation from the requirement that the records are to be kept on their establishment concerned, as set out in the first subparagraph, when it is physically not possible to keep the records on that establishment, they shall be kept in the office from which the business is administered.

#### *Article 187*

### **Record-keeping obligations of disease control aquatic food establishments**

1 Operators of disease control aquatic food establishments subject to approval in accordance with Article 179 shall keep and maintain records of:

- a all movements into and from their establishment of aquaculture animals and products of animal origin obtained from such animals;
- b discharge of water and relevant biosecurity measures.

2 Operators of disease control aquatic food establishments shall:

- a keep the records provided for in paragraph 1 on their establishment and shall make them available to the competent authority on request;
- b retain those records for a minimum period to be prescribed by the competent authority, which may not be less than three years.

The records shall be kept and maintained in paper or electronic form.

#### *Article 188*

### **Record-keeping obligations of transporters**

1 Transporters of aquatic animals intended for aquaculture establishments or to be released into the wild shall keep and maintain records in relation to:

- a the species, categories and quantities (numbers, volume or weight) of aquatic animals transported by them;
- b mortality rates of the aquaculture animals and wild aquatic animals in question during transport, in so far as is practicable for the type of transport and the species of aquaculture animals and wild aquatic animals transported;
- c aquaculture establishments and disease control aquatic food establishments visited by the means of transport;
- d any exchange of water that took place during transport, specifying the sources of new water and sites of release of water;
- e the cleaning and disinfection of the means of transport.

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The records shall be kept and maintained in paper or electronic form.

2 Transporters presenting a low risk of spreading listed or emerging diseases may be exempted by the Member State concerned from the requirement to keep records of all or some of the information listed in paragraph 1, provided that traceability is ensured.

3 Transporters shall keep the records provided for in paragraph 1:

- a in such a manner that they can be made immediately available to the competent authority on request;
- b for a minimum period to be prescribed by the competent authority, which may not be less than three years.

### *Article 189*

#### **Delegation of powers concerning record-keeping**

1 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning rules supplementing the record-keeping requirements provided for in Articles 186, 187 and 188, as regards information to be recorded by operators in addition to that provided for in Articles 186(1), 187(1) and 188(1).

2 The Commission shall take the following matters into account when adopting the delegated acts provided for in paragraph 1:

- a the risks posed by each type of aquaculture establishment or transport;
- b the species and categories of aquatic animals kept on the aquaculture establishment concerned, or transported to or from that establishment;
- c the type of production of the establishment;
- d typical movement patterns for the type of aquaculture establishment or disease control aquatic food establishment;
- e the numbers, volume or weight of aquatic animals kept on the establishment or transported to or from it.

### *Article 190*

#### **Implementing powers concerning exemptions from the record-keeping requirements**

The Commission may, by means of implementing acts, lay down rules concerning the types of aquaculture establishments and operators that may be exempted by Member States from the record-keeping requirements provided for in Articles 186 and 188, as regards:

- (a) operators of certain categories of aquaculture establishments and transporters;
- (b) aquaculture establishments keeping, or transporters transporting, respectively, a small number of aquaculture animals or a small number of aquatic animals;
- (c) certain species and categories of aquatic animals.

When adopting those implementing acts, the Commission shall base those acts on the criteria provided for in Article 189(2).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

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- (1) Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin ([OJ L 139, 30.4.2004, p. 55](#)).

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